

IPS InLine®

IPS InLine® Konventionelle Metallkeramik

IPS InLine® One Einsicht-Metallkeramik

IPS InLine® PoM Press-on-Metal Keramik



Scientific Documentation

Table of Contents

1. Introduction.....	3
2. Basic materials science	5
2.1 Fabrication of feldspar ceramics.....	5
3. Material description	6
3.1 IPS InLine – the conventional metal-ceramic.....	6
3.2 IPS InLine PoM – the press-on-metal ceramic	7
3.3 Shade, Stains and Glaze materials.....	8
3.4 Metal-ceramic bond	8
4. Technical Data	11
5. Investigations of the material properties	17
5.1 Biaxial flexural strength (internal measurement)	17
5.2 Material data of IPS InLine PoM – Press-on-Metal ceramic.....	17
5.3 Volume shrinkage	18
5.4 Thermal expansion	19
5.5 Physical properties	21
6. In vitro investigation.....	23
6.1 Introduction	23
6.2 In vitro wear tests in the chewing simulator	23
6.3 Metal-ceramic bond	26
6.4 List of alloys for the IPS InLine System.....	28
6.5 Metal-ceramic bond (re-cast alloys).....	29
7. Clinical evaluation of the IPS InLine System	30
7.1 Clinical data	30
7.2 Clinical studies with IPS InLine (conventional metal-ceramic).....	30
7.3 Clinical studies with IPS InLine PoM (Press-on-Metal ceramic)	30
8. Biocompatibility	32
8.1 Introduction	32
8.2 Biocompatibility	32
8.3 Chemical solubility	33
8.4 In vitro cytotoxicity	33
8.5 Radioactivity.....	33
8.6 Sensitization, irritation	34
8.7 Biological risk to user and patient	34
8.8 Conclusion.....	34
9. Literature.....	35

1. Introduction

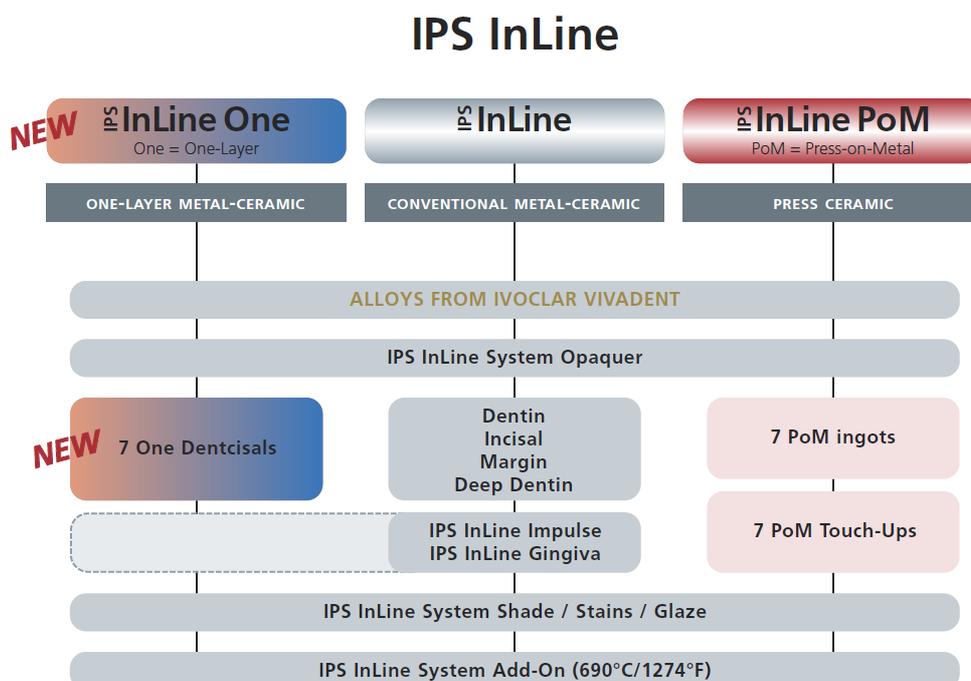
IPS InLine One (one-layer metal-ceramic), *IPS InLine (conventional metal-ceramic)* and *IPS InLine PoM (Press-on-Metal)* are veneering ceramics for alloys. The materials are leucite ceramics.

IPS InLine One is a one-layer metal-ceramic. IPS InLine One are one-layer materials which are based on the existing raw materials used for IPS InLine. These layering materials are named "Dentcisal" – they represent a combination of dentin and incisal materials and feature corresponding properties in terms of chroma and translucency. These components allow users to create lifelike restorations quickly and efficiently.

IPS InLine is a conventional metal-ceramic. Suitable manufacturing processes and a specific grain size distribution form the basis for the development. The result is a product featuring good firing stability, low shrinkage and easy processing for the fabrication of highly esthetic restorations.

IPS InLine PoM is a Press-on-Metal ceramic. Thus, it is possible to optimally combine the advantages of the casting and the press techniques. Compared to the layering technique, the wax-up of IPS InLine PoM in the press-on-metal technique corresponds to the final shape. There is no need for cut-back or ceramic layering. Apply the opaquer, complete the wax-up, press the fully anatomical restoration and characterize it with the stain materials and glaze.

The systems concept:



Indications:*IPS InLine One*

- One-layer veneering ceramic for the most popular dental alloys in the CTE range of $13.8 - 15.0 \times 10^{-6}/K$ (25-500°C)

IPS InLine

- Conventional multi-layer veneering ceramic for the most popular dental alloys in the CTE range of $13.8 - 15.0 \times 10^{-6}/K$ (25-500°C)
- Veneers on refractory dies

IPS InLine PoM

- Fully anatomical pressing on masked (opaquerized) metal crown and bridge frameworks
- Pressing on dental alloys in the CTE range of $13.8 - 14.5 \times 10^{-6}/K$ (25-500°C) with a silver content of <10%

2. Basic materials science

Conventional dental ceramics are based on a ternary materials system consisting of clay/kaolin, feldspar and quartz. Dental ceramics considerably differ from household ceramics. As illustrated in the figure below (Fig. 1), dental ceramics have a high content of feldspar and a low content of kaolin. Exactly the opposite is true for household ceramics.

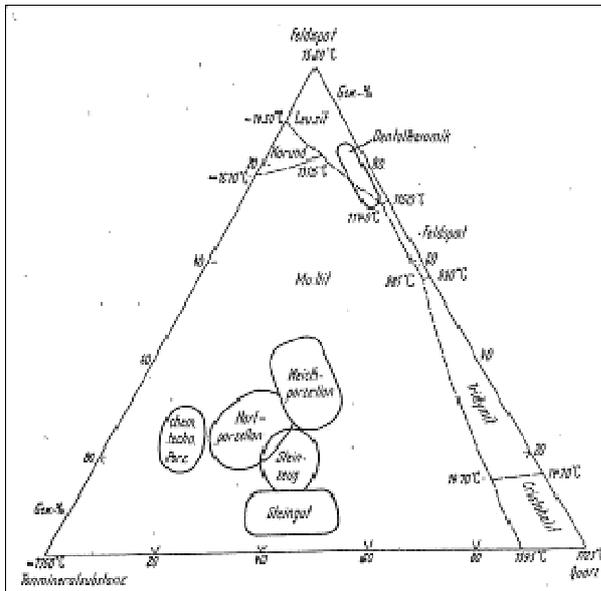


Fig. 1: Ternary materials system: clay - feldspar - quartz [1]

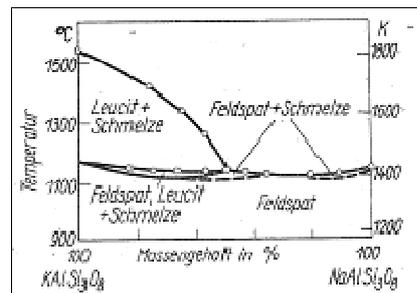


Fig. 2: Phase diagram orthoclase-albite [2]

Feldspathic ceramics are in part based on naturally occurring raw materials (feldspar). Natural feldspars are, for example, potassium feldspar ($K_2Al_3Si_6O_8$; orthoclase) and sodium feldspar ($NaAlSi_3O_8$; albite). Potassium feldspar imparts dental ceramics with high hardness, increased thermal expansion and chemical durability. In general, dental ceramics contain a high proportion of potassium feldspar. Potassium feldspar is responsible for the formation of leucite crystals, which provide resistance to excessive pyroplastic flow during the melting process. The constitution diagram (Fig. 2) shows that potassium feldspar does not immediately become a liquid when the melting point is reached. Instead, a mixture consisting of a liquid phase and leucite crystals forms over a fairly wide temperature range. This phase exhibits a very high viscosity, i.e. it is resistant to flow. The wide firing range imparts the fired objects with a favourable stability [1; 3].

The leucite crystals embedded in the glass matrix increase the strength of the restoration. The propagation of cracks is slowed or deflected by the leucite crystals. In the process, the crystalline phase absorbs fracture energy. As a result, the propagation of cracks is arrested or slowed down.

2.1 Fabrication of feldspar ceramics

In contrast to synthetic leucite ceramics, feldspar ceramics contain naturally occurring feldspar as the base material.

Natural feldspar and glass-forming chemicals are milled, mixed and melted. Quenching this melt results in the formation of a glass with the desired chemical composition. Renewed milling of the glass (possibly in combination with other glass powders) produces a glass powder which is the basis for further processing of the final leucite ceramic. The glass powders are mixed and treated according to a procedure which is subsequently defined (sintering / tempering). Thus, the content of leucite in the end product is controlled. In order

to stop the precipitation process of leucite at the right time, the mixture is quenched. The final product is obtained by further grinding and sieving.

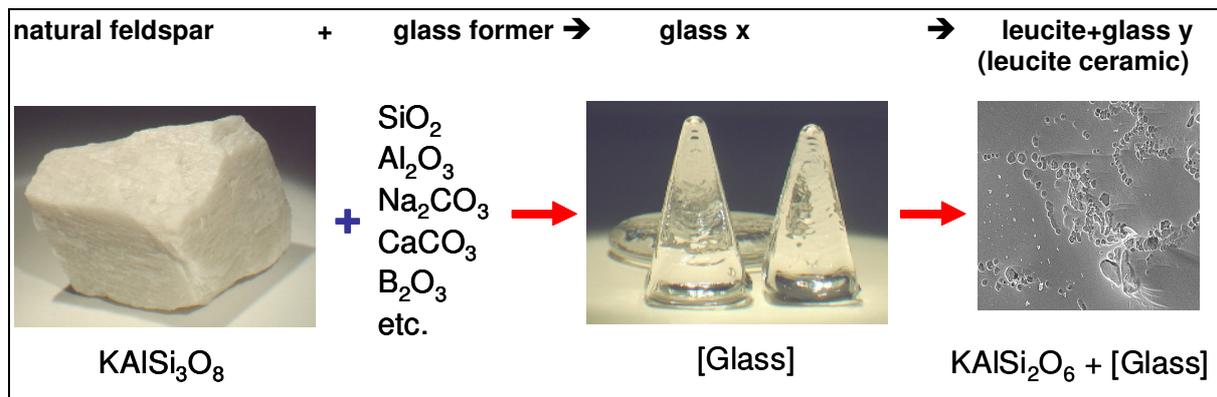


Fig. 3: Fabrication of feldspar ceramics

3. Material description

3.1 IPS InLine – the conventional metal-ceramic

The microstructure of *IPS InLine* consists of a glassy matrix and leucite crystals.

The SEM images of polished and etched surfaces reveal the microstructure of the material. Depending on the magnification, different phases (glass/crystal), grain sizes, grain boundaries and defects (e.g. pores, cracks) are discernible, as shown in the following set of images (Figs 4 to 6). Leucite is the result of surface crystallization. Therefore, the leucite crystals are located along the grain boundaries. The small leucite crystals that are arranged like strings of beads show the former grain boundaries prior to tempering/sintering (see Figs 7a and 7b).

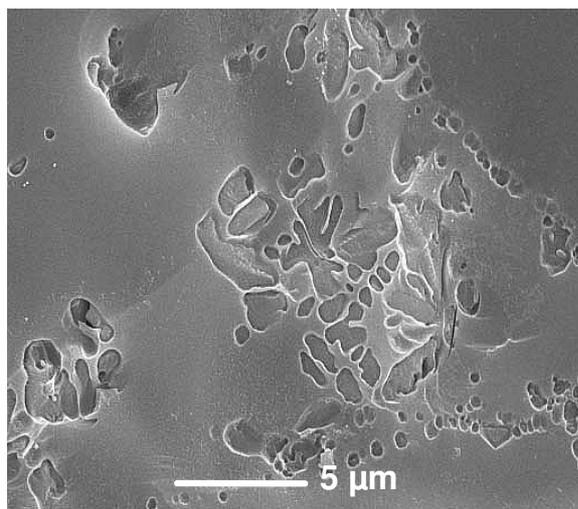
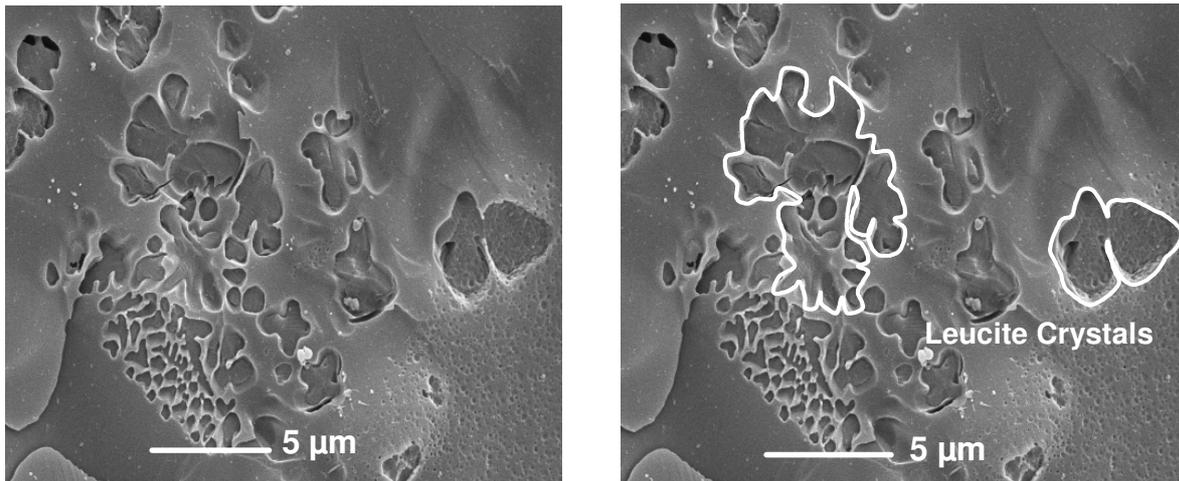


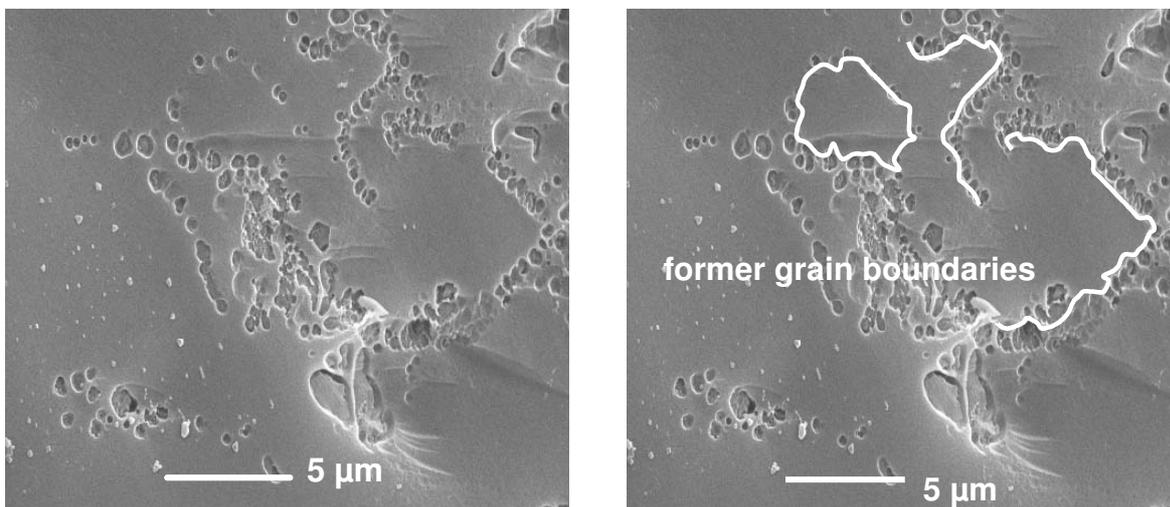
Fig. 4: *IPS InLine* Dentin A2; 5000x, etched. A specially designed etching technique dissolves the leucite crystals more quickly than the glass.



Figs 5 and 5a: IPS InLine Dentin A3; 5000x, etched. Glass matrix and leucite crystals are visible. Both images show the same section. In Fig. 5b, the leucite crystals have been highlighted.



Fig. 6: Middle section of Fig. 5 (magnified) The striation in the dissolved areas shows the lamellar structure of leucite crystals – a result of dendritic growth.



Figs 7a and 7b: IPS InLine Incisal T11; 5000x Same section, image 7b shows the grain boundaries.

3.2 IPS InLine PoM – the press-on-metal ceramic

The Press-on-Metal ingot is composed of a leucite-containing ceramic (Fig. 8), the optical properties of which are optimized by small shares of further crystal phases.

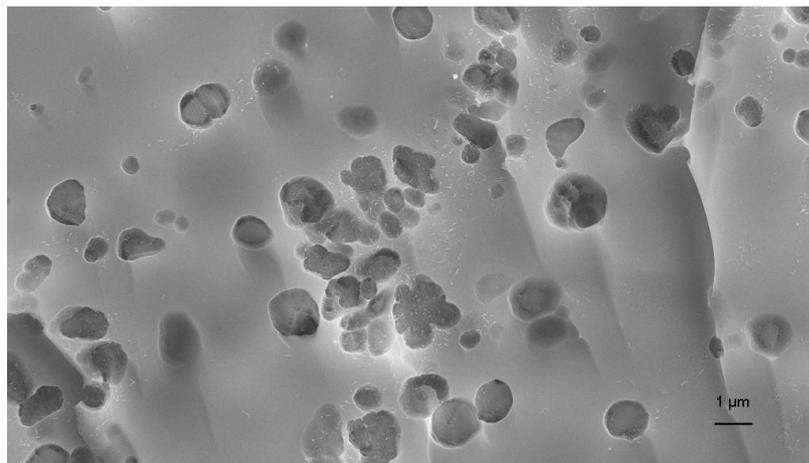


Fig. 8: Microstructure of IPS InLine PoM (etched, 10 sec with 3% hydrofluoric acid)

The colour of the press material is completed by ceramic colour pigments. The base material in powder form is fired to monolithic press ingots after shaping them under vacuum. A homogeneous and non-porous microstructure is achieved by the press procedure. The firing stability of the ingot allows Touch Up materials, Shades, Stains and Glaze materials to be applied without compromising the accuracy of fit of the restoration.

The Touch Up materials are leucite-containing ceramics which are pigmented according to the ingot shade concept. The coefficient of thermal expansion and firing temperature are adjusted to an application in the cervical and incisal area after pressing and prior to the characterization firing cycles.

3.3 Shade, Stains and Glaze materials

The new Shades, Stains and Glaze materials are based on very fine-grained glass powders, which are sintered at low temperatures. While the Glaze material is composed of the pure, unpigmented glass powder, specifically prepared colour pigments are added to the Shades and Stains. The powder materials are dispersed to a paste with organic thickening agents in order to facilitate the application for the dental technician.

3.4 Metal-ceramic bond

3.4.1 Bond mechanisms

Good wettability of the alloy surface by the opaquer, which is very viscous at high temperatures, is a prerequisite for an optimal bond. Basically, however, the metal-ceramic bond is based on adhesion, i.e. the bonding effect between a solid interface (here: metal surface) and a second phase (here: the ceramic). The most important of the numerous adhesive mechanisms are described below¹:

– Adhesion by mechanical bond

The ceramic bonds mechanically to the metal surface by filling depressions and/or enclosing protruding structures and anchor points, which are present on the surface after metal conditioning. In addition to this mechanical bond, the ceramic demonstrates a certain compressive strain, since its coefficient of thermal expansion is lower than that of the alloy.

¹ "Focus on: Alloy/ceramic bond, IPS InLine", Ivoclar Vivadent AG, 2005

– Adhesion by chemical bond

Processes such as chemical reactions, dissolution processes, redox processes, diffusion and precipitation result in the formation of a characteristic transition area at the interface between metal and ceramic. Particularly in the presence of non-precious alloy components, a certain saturation of both metal and ceramic with metal oxides occurs. Ideally, this results in the formation of an oxide monolayer, which is a component of both the metal and the ceramic. The resulting bond energies and electronic structures are then identical at each point of the interface. The prerequisite for this behaviour is an oxide layer that is formed on the metal surface during oxide firing.

This bonding mechanism can be depicted using the following model.

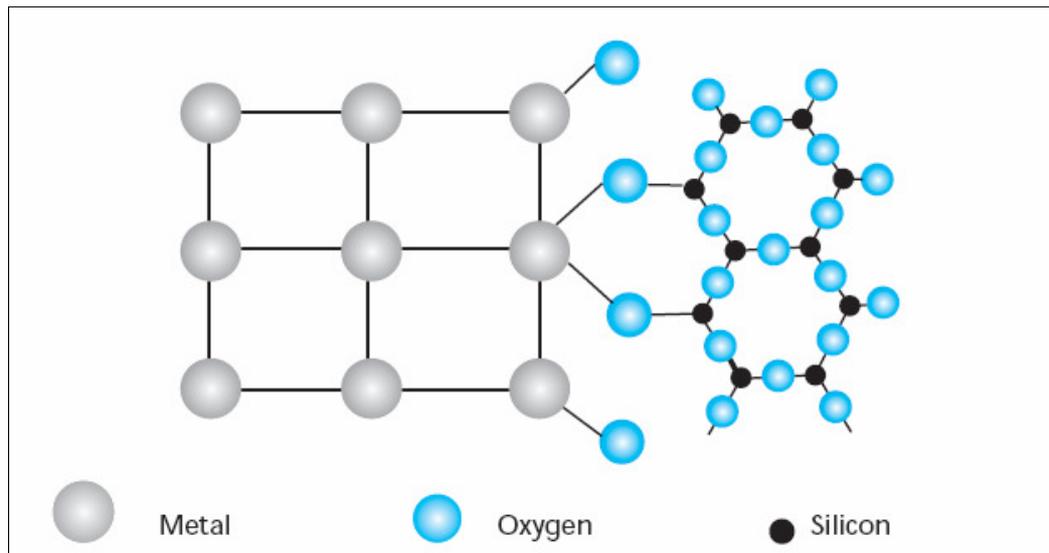


Fig. 9: Model of the chemical bond²

The chemical bond is initiated by oxygen atoms which are present in both the metal layer and the ceramic and thus link the two materials.

– Adhesion by intermolecular forces

Short-range forces act between the alloy and ceramic, which in their sum are called Van der Waals forces. Their contribution to the adhesive bond is smaller than that of the mechanical and chemical bond.

3.4.2 Bond of metal to IPS InLine System

A metal-ceramic restoration is a material composition that is based on a durable bond between an alloy and a ceramic material. The interface between metal and ceramic is formed by the opaquer, which, if carefully applied and fired, produces a sound bond between the two materials. The following images (Fig. 10, Fig. 11) show the transition areas between alloy, opaquer and ceramic for a high-gold and a base-metal alloy. The fine-grain structure of the opaquer is clearly visible. At high magnification, the alloy surface appears rough and covered with depressions filled with ceramic material. This pattern plays an important role for the metal-ceramic bond.

The quality of the metal-ceramic bond for IPS InLine (Fig. 10) and IPS InLine PoM (Fig. 11) is good and very homogeneous.

² Schnettger A., Fachhochschule Osnabrück 2004

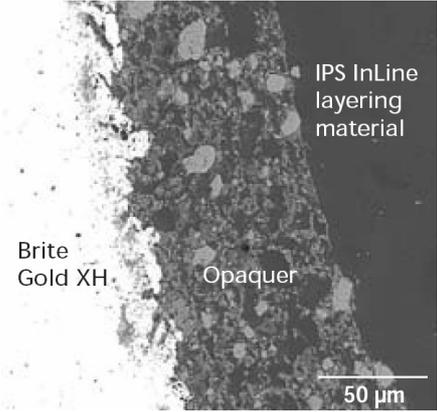


Fig. 10: Bond of Brite Gold XH / IPS InLine

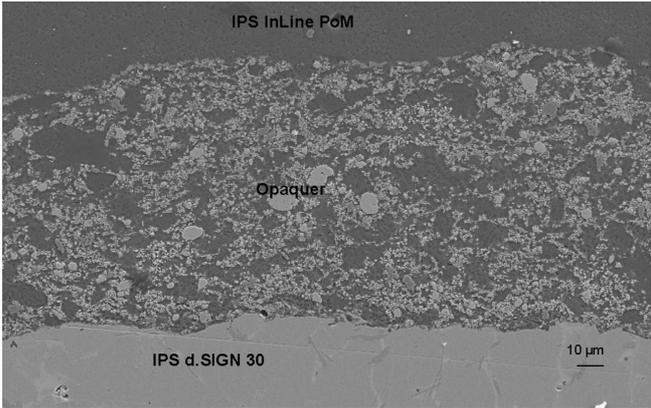


Fig. 11: Bond of IPS d.SIGN30 / IPS InLine PoM

4. Technical Data

IPS InLine

Dentin, Deep Dentin, Occlusal Dentin, Incisal, Transpa Incisal, Cervical Incisal, Transpa, Gingiva, Intensive Gingiva, Mamelon, Add-On Margin

<u>Standard composition:</u>	(in wt%)
SiO ₂	59.5 - 65.5
Al ₂ O ₃	13.0 - 18.0
K ₂ O	10.0 - 14.0
Na ₂ O	4.0 - 8.0
Other oxides	0.0 - 4.0
Pigments	0.0 - 2.0

Physical properties:

In accordance with:

ISO 6872 Dental ceramic

ISO 9693 Metal-ceramic dental restorative systems

Flexural strength		80 ± 20 MPa
Chemical solubility		< 100 µg/cm ²
Coefficient of thermal expansion (25 - 500 °C)	2 firings	12.60 ± 0.5 10 ⁻⁶ K ⁻¹
	4 firings	13.20 ± 0.5 10 ⁻⁶ K ⁻¹
Glass transition temperature	2 firings	585 ± 10 °C
	4 firings	585 ± 10 °C

IPS InLine One

Dentcisal

Standard composition:

(in wt%)

SiO ₂	59.5 - 65.5
Al ₂ O ₃	13.0 - 18.0
K ₂ O	10.0 - 14.0
Na ₂ O	4.0 - 8.0
Other oxides	0.0 - 4.0
Pigments	0.0 - 2.0

Physical properties:

In accordance with:

ISO 6872 Dental ceramic

ISO 9693 Metal-ceramic dental restorative systems

Flexural strength		80 ± 20 MPa
Chemical solubility		< 100 µg/cm ²
Coefficient of thermal expansion (25 - 500 °C)	2 firings	12.60 ± 0.5 10 ⁻⁶ K ⁻¹
	4 firings	13.20 ± 0.5 10 ⁻⁶ K ⁻¹
Glass transition temperature	2 firings	585 ± 10 °C
	4 firings	585 ± 10 °C

IPS InLine PoM Ingot

PoM BL, PoM 1 - 6

Standard composition:

(in wt%)

SiO ₂	50.0 - 65.0
Al ₂ O ₃	8.0 - 20.0
Na ₂ O	4.0 - 12.0
K ₂ O	7.0 - 13.0
Other oxides, fluoride	0.0 - 6.0
Pigments	0.0 - 3.0

Physical properties:

In accordance with:

ISO 6872 Dental ceramic

ISO 9693 Metal-ceramic dental restorative systems

Flexural strength		130 ± 20 MPa
Chemical solubility		< 60 µg/cm ²
Coefficient of thermal expansion (25-500 °C)	2 firings	13.0 ± 0.5 10 ⁻⁶ K ⁻¹
	4 firings	13.3 ± 0.5 10 ⁻⁶ K ⁻¹
Glass transition temperature	2 firings	575 ± 10 °C
	4 firings	575 ± 10 °C

IPS InLine PoM Touch Up

PoM Touch Up BL, PoM Touch Up 1 - 6

Standard composition:

(in wt%)

SiO ₂	50.0 - 65.0
Al ₂ O ₃	8.0 - 20.0
Na ₂ O	4.0 - 12.0
K ₂ O	7.0 - 13.0
Other oxides, fluoride	0.0 - 6.0
Pigments	0.0 - 3.0

Physical properties:

In accordance with:

ISO 6872 Dental ceramic

ISO 9693 Metal-ceramic dental restorative systems

Flexural strength		80 ± 20 MPa
Chemical solubility		< 60 µg/cm ²
Coefficient of thermal expansion (25-500 °C)	2 firings	12.0 ± 0.5 10 ⁻⁶ K ⁻¹
	4 firings	12.6 ± 0.5 10 ⁻⁶ K ⁻¹
Glass transition temperature	2 firings	540 ± 10 °C
	4 firings	540 ± 10 °C

IPS InLine System

Opaquer, Intensive Opaquer,

Opaquer F

<u>Standard composition:</u>	(in wt%)	Opaquer Intensive Opaquer	Opaquer F
Al ₂ O ₃		8.0 - 14.0	8.0 - 14.0
SiO ₂		35.0 - 55.0	35.0 - 55.0
K ₂ O		7.5 - 13.0	7.5 - 13.0
Na ₂ O		3.5 - 5.5	3.5 - 5.5
ZrO ₂		14.0 - 39.0	0.0 - 2.0
Other oxides		0.0 - 3.0	0.0 - 3.0
Pigments		4.0 - 20.0	4.0 - 20.0
Glycols		26.0	26.0

Physical properties:

In accordance with:

ISO 6872 Dental ceramic

ISO 9693 Metal-ceramic dental restorative systems

	Opaquer Intensive Opaquer	Opaquer F
Chemical solubility	< 100	< 100 µg/cm ²
Coefficient of thermal expansion (25 - 500 °C)		
2 firings	13.50 ± 0.5	13.60 ± 0.5 10 ⁻⁶ K ⁻¹
4 firings	13.70 ± 0.5	13.90 ± 0.5 10 ⁻⁶ K ⁻¹
Glass transition temperature		
2 firings	605 ± 10	590 ± 10 °C
4 firings	605 ± 10	590 ± 10 °C

IPS InLine System

Shade, Stains, Glaze materials

Standard composition:

	Shades: [in wt%]	Stains [wt%]	Glaze [wt%]
SiO ₂	61.0 - 68.0	61.0 - 68.0	61.0 - 68.0
Al ₂ O ₃	5.0 - 8.0	5.0 - 8.0	5.0 - 8.0
Na ₂ O	5.0 - 8.0	5.0 - 8.0	5.0 - 8.0
K ₂ O	5.0 - 8.0	5.0 - 8.0	5.0 - 8.0
ZnO	2.0 - 4.0	2.0 - 4.0	2.0 - 4.0
Other oxides	3.5 - 17.0	3.5 - 17.0	3.5 - 17.0
Pigments	0.4 - 25.0	0.4 - 25.0	0.0 - 1.0
Glycols	30.0 - 40.0	30.0 - 40.0	30.0 - 40.0

Physical properties:

In accordance with:

ISO 6872 Dental ceramic

ISO 9693 Metal-ceramic dental restorative systems

		Shades	Stains	Glazing	
Chemical solubility		μg/cm ²	< 100	< 100	< 100
Coefficient of thermal expansion (25 - 400 °C)	2 firings	10 ⁻⁶ K ⁻¹	9.4 ± 0.5	9.4 ± 0.5	9.4 ± 0.5
	4 firings	10 ⁻⁶ K ⁻¹	9.6 ± 0.5	9.6 ± 0.5	9.6 ± 0.5
Glass transition temperature		°C	475 ± 10	475 ± 10	470 ± 10

5. Investigations of the material properties

5.1 Biaxial flexural strength (internal measurement)

The biaxial flexural strength of the IPS InLine range of products has been determined by Ivoclar Vivadent according to EN ISO 9693.

Material	Biaxial flexural strength	Threshold value EN ISO 9693
IPS InLine Opaquer A3	168 MPa	50 MPa
IPS InLine Dentin A2	92 MPa	50 MPa
IPS InLine Incisal TI2	96 MPa	50 MPa

Tab. 1: Biaxial flexural strength values of the IPS InLine products (internal measurement, Ivoclar Vivadent AG Schaan, 2004)

- The biaxial flexural strength values of IPS InLine are clearly above the minimum values stipulated in the ISO standard.

5.2 Material data of IPS InLine PoM – Press-on-Metal ceramic

Feature	IPS InLine PoM	Threshold value ISO 9693
CTE (100-500 °C), pressed	$13.4 \cdot 10^{-6} \text{K}^{-1}$	
TG, pressed	571 °C	
CTE (100-500 °C), simulated multiple firing cycles (840 °C/ 840 °C/ 770 °C/ 770 °C/ 770 °C)	$13.7 \cdot 10^{-6} \text{K}^{-1}$	
TG, simulated multiple firing cycles (840 °C/ 840 °C/ 770 °C/ 770 °C/ 770 °C)	578 °C	
Density	2.52 g/cm ³	
Chemical solubility	50 µg/cm ²	< 100 µg/cm ²
Biaxial flexural strength	130 ± 20 MPa	> 50 MPa
Fracture toughness	0.9 ± 0.3 MPa·m ^{1/2}	
Vickers hardness HV 0.2	600	
Martens hardness	2900 ± 400 MPa	

Tab. 2: Material data IPS InLine PoM

5.3 Volume shrinkage

Sintering of objects made of pressed ceramic powders results in shrinkage of the object, as the powder particles fuse together and the porosity considerably decreases. A distinction is drawn between linear shrinkage and volume shrinkage (Fig. 12).

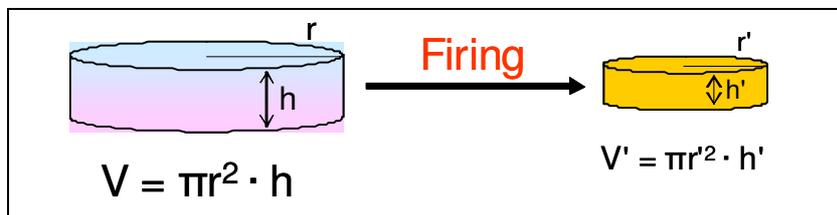


Fig. 12: Volume shrinkage as a result of sintering

The volume shrinkage ΔV is calculated as follows: $\Delta V (\%) = (V - V') / V \times 100$

Due to the lower volume shrinkage, processing of the material becomes easier, faster and more reliable for the dental technician. The volume shrinkage of IPS InLine, IPS Classic and three competitive materials was measured in an internal investigation.

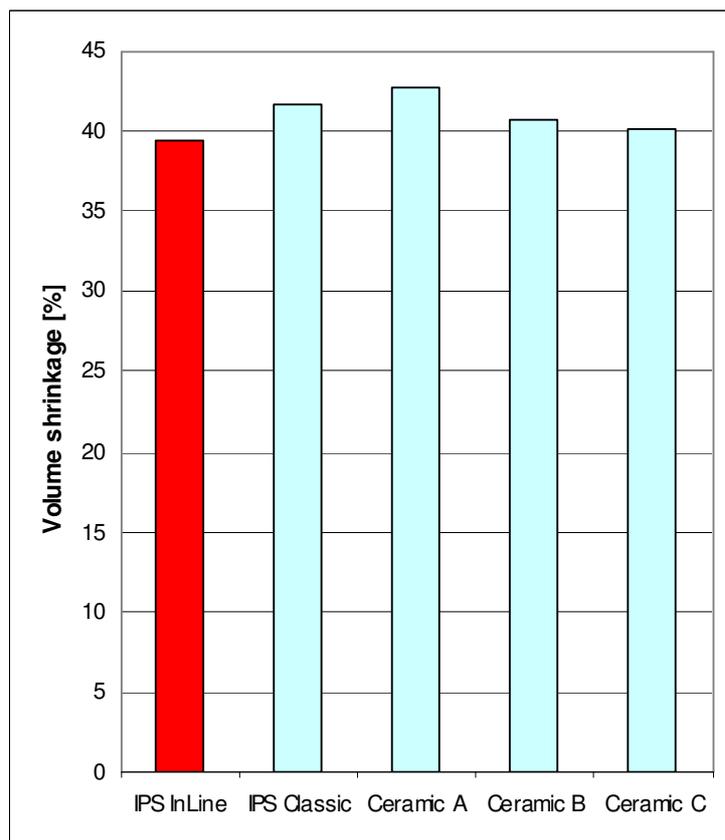


Fig. 13: Volume shrinkage of various ceramics (internal measurement, Ivoclar Vivadent AG, Schaan, 2004)

- IPS InLine features optimum shrinkage. The values are in the range of proven layering ceramics.

5.4 Thermal expansion

5.4.1 The linear coefficient of thermal expansion (CTE)

The linear thermal expansion of a material is determined by means of a dilatometer. The specimen is continuously heated/cooled and the linear dimensional change recorded. The resulting dimensional change can be continuous or erratic. A jump in the curve can be seen if a phase transition occurs in the material. The linear coefficient of thermal expansion (CTE) is determined per unit length for 1 degree change in temperature (1 Kelvin). The CTE largely depends on the temperature range within which it is measured. Therefore, the temperature range has to be stated at all times. The CTE for dental ceramics is analyzed in the range up to the glass transition temperature T_G . The CTE serves to assess the possible loading of the ceramic in combination with the framework/layering material. Glass-ceramics at temperatures above the T_G value are soft and the stress is dissipated by the flow of the material.

The unit of the CTE is [$10^{-6} \cdot K^{-1}$] according to ISO 9693. However, [$1 \mu m/m \cdot K$] is also commonly used.

5.4.2 CTE of ceramic and metal

The thermal expansion of the ceramic is decisive for its compatibility with various framework materials. Ceramic materials are less sensitive to compressive stresses than to tensile stresses. Therefore, in dental restorations the ceramic has to be applied in such a way that it is subjected to compressive stress in the restoration. This is achieved by choosing the CTE of the ceramic to be about one unit ($1 \times 10^{-6} \cdot K^{-1}$) lower than the CTE of the alloy.

The CTE of the ceramic changes with the thermal treatment (e.g. with the number of firing cycles), as the structure may change depending on the temperature (grain growth, precipitation of a higher amount of leucite).

5.4.3 Influence of the thermal treatment on the CTE

IPS InLine is suitable for alloys in the CTE range of $13.8-15.0 \times 10^{-6} \cdot K^{-1}$ (25/500°C). The CTE of the ceramic can be adjusted to the alloys in a certain range by thermal treatment, e.g. by several firing cycles, long-term cooling or tempering (holding at an increased temperature). For an optimum restoration, it is therefore important to observe the recommendations of the manufacturer as regards the alloys and specifications on thermal treatment.

Fig. 14 shows the influence of thermal treatment on the CTE.

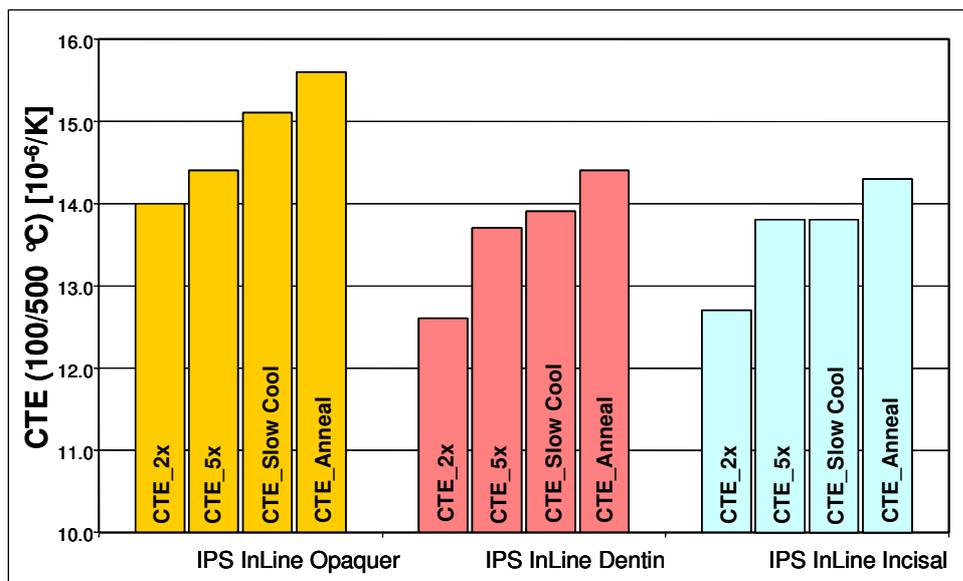


Fig. 14: Change in the CTE of IPS InLine as a function of different thermal treatments (INDEX: 2x; 5x: Number of firing cycles; SlowCool: Long-term cooling; Anneal: Temper) (internal measurement, Ivoclar Vivadent AG, Schaan, 2004)

The change in the CTE by thermal treatment depends on the ceramic type and may vary according to the material. The following chart (Fig. 15) illustrates the differences.

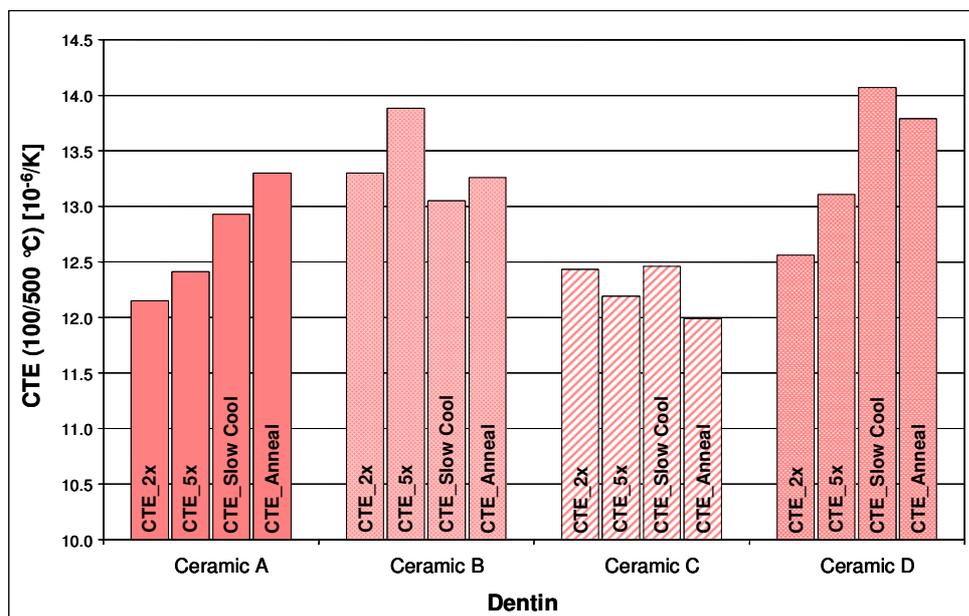


Fig. 15: Change in the CTE of different ceramics (Dentin) as a function of different thermal treatments (INDEX: 2x; 5x: Number of firing cycles; SlowCool: Long-term cooling; Anneal: Temper); (internal measurement, Ivoclar Vivadent AG, Schaan, 2004)

5.5 Physical properties

Sinmazisik *et al.* examined the microstructure and physical properties of six ceramic veneering materials [4]. Below are the results of hardness measurements and flexural strength values of sintered test samples.

5.5.1 Biaxial flexural strength

The biaxial flexural strength was determined according to ASTM standard F394-78. Seven test samples per material were tested by means of a universal testing machine.

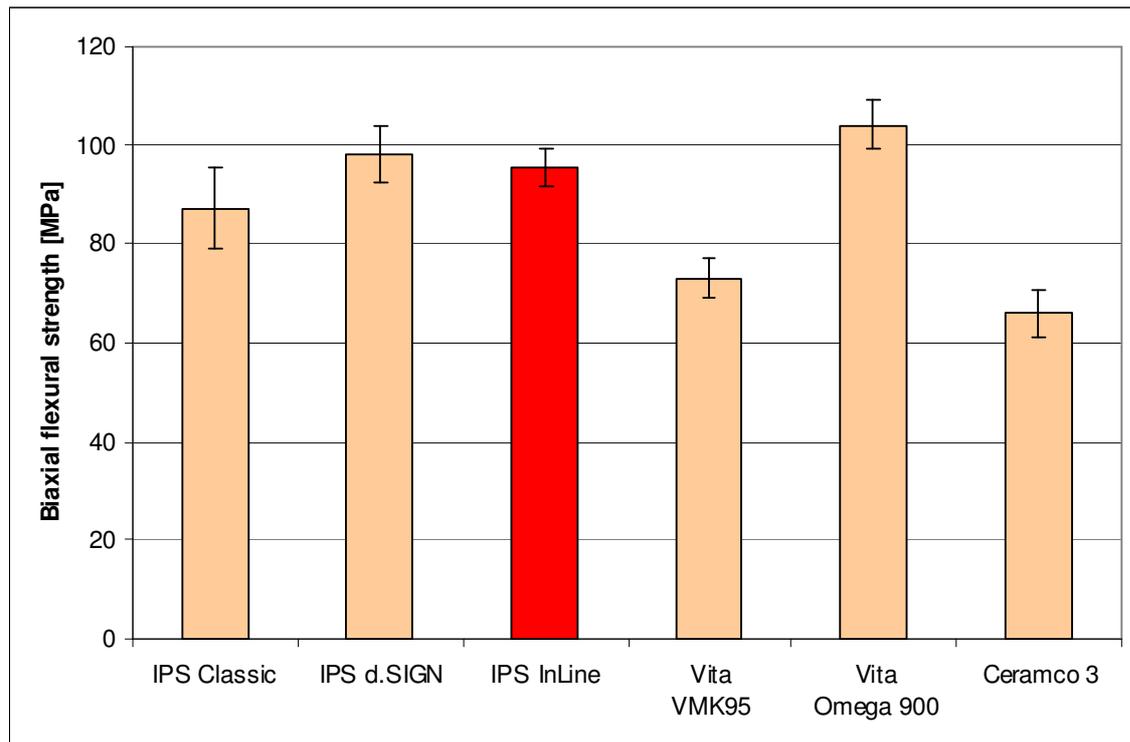


Fig. 16: Biaxial flexural strength values of ceramic veneering materials [4]

- In comparison with the values of other products, the biaxial flexural strength values found for IPS InLine are in the upper range.

5.5.2 Microhardness

The hardness was measured in a microhardness test unit. The load of 500 g was applied by means of the Vickers diamond indenter for 20 S. Ten to 12 impressions were produced in 4 test samples per material to determine the hardness.

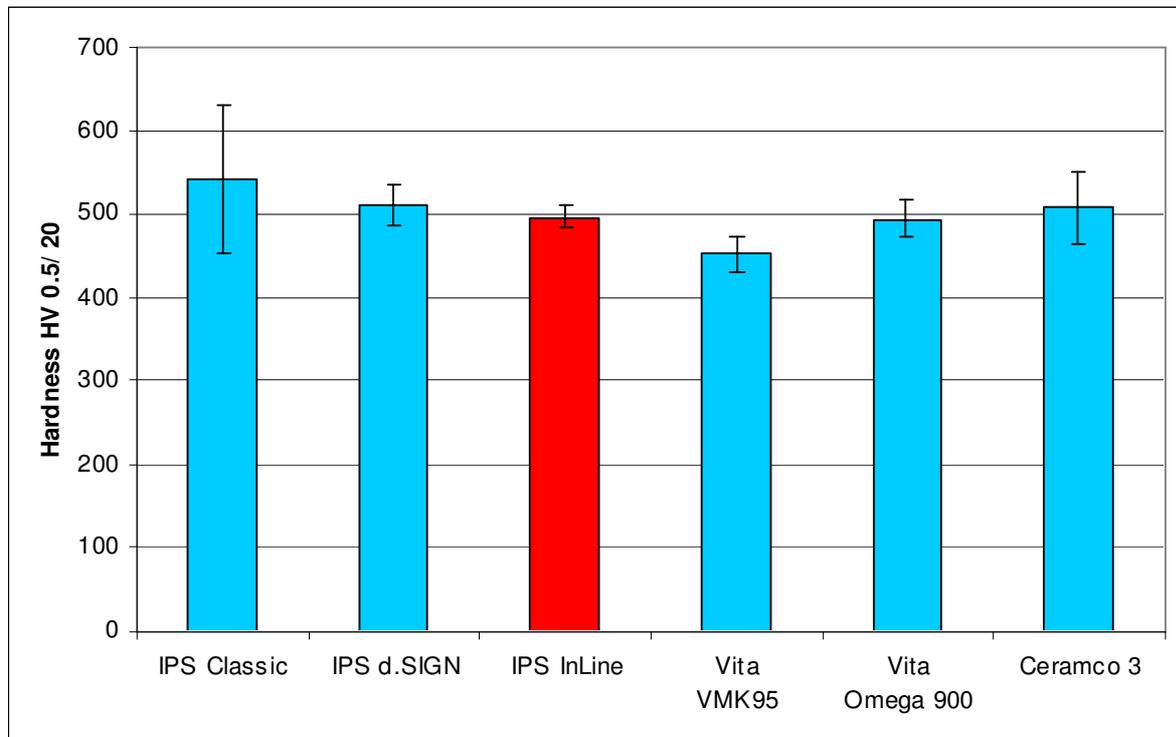


Fig. 17: Hardness values of ceramic veneering materials [4]

- The variation of the hardness values is relatively wide. On the one hand this is due to the testing method, but depends also on the homogeneity and grain size of the microstructure. IPS InLine showed the smallest variation.

6. In vitro investigation

6.1 Introduction

Although the results of these *in vitro* examinations cannot always be directly applied to the clinical application of the material, they provide important information about how the product will behave under certain test conditions.

6.2 In vitro wear tests in the chewing simulator

Standardized molar crowns which have been adhesively bonded to PMMA dies are subjected to 120,000 mastication cycles at a load of 50 N. The load is eccentric with a horizontal movement of 0.7 mm. Additionally, the crowns are subjected to a temperature change of 5%/55°C every 105 seconds.

Palatal enamel cusps of human upper molars are used as antagonists.

6.2.1 IPS InLine: Maximum vertical wear

Material wear:

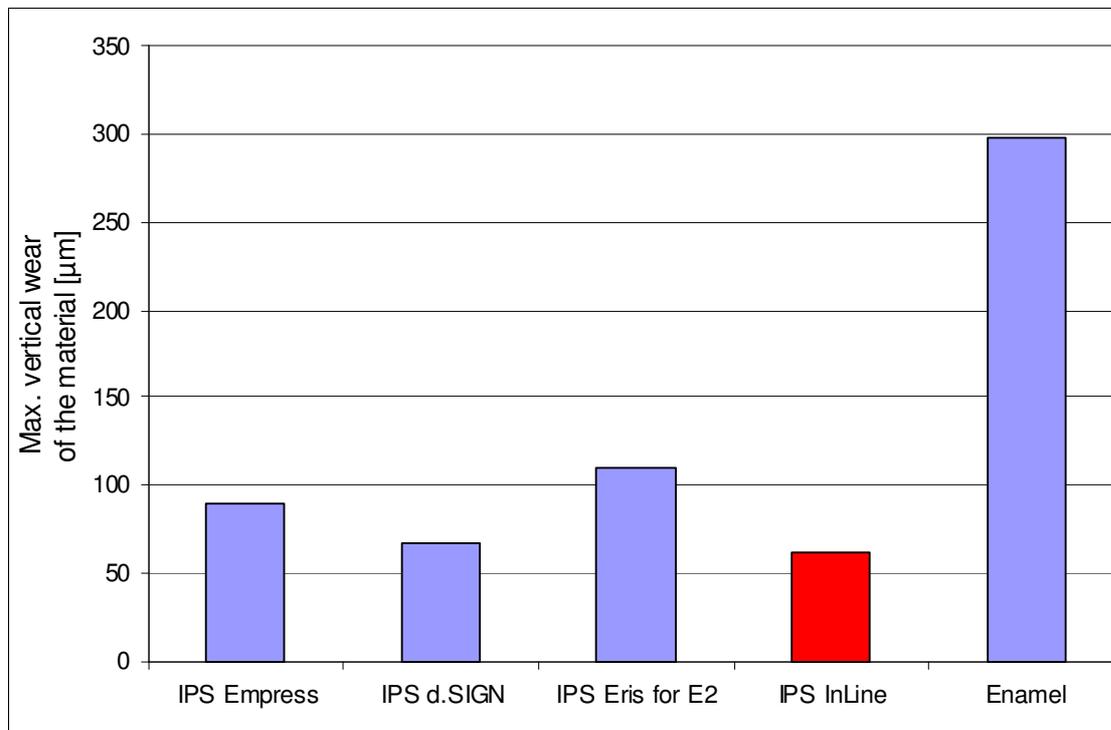


Fig. 18: In vitro tests in the chewing simulator: Material wear (R&D, Ivoclar Vivadent AG, Schaan, 2004)

- IPS InLine, as well as other time-tested products from Ivoclar Vivadent, exhibit a lower material wear than human enamel under the present test conditions. The differences can be attributed to the different material compositions.

Antagonist wear:

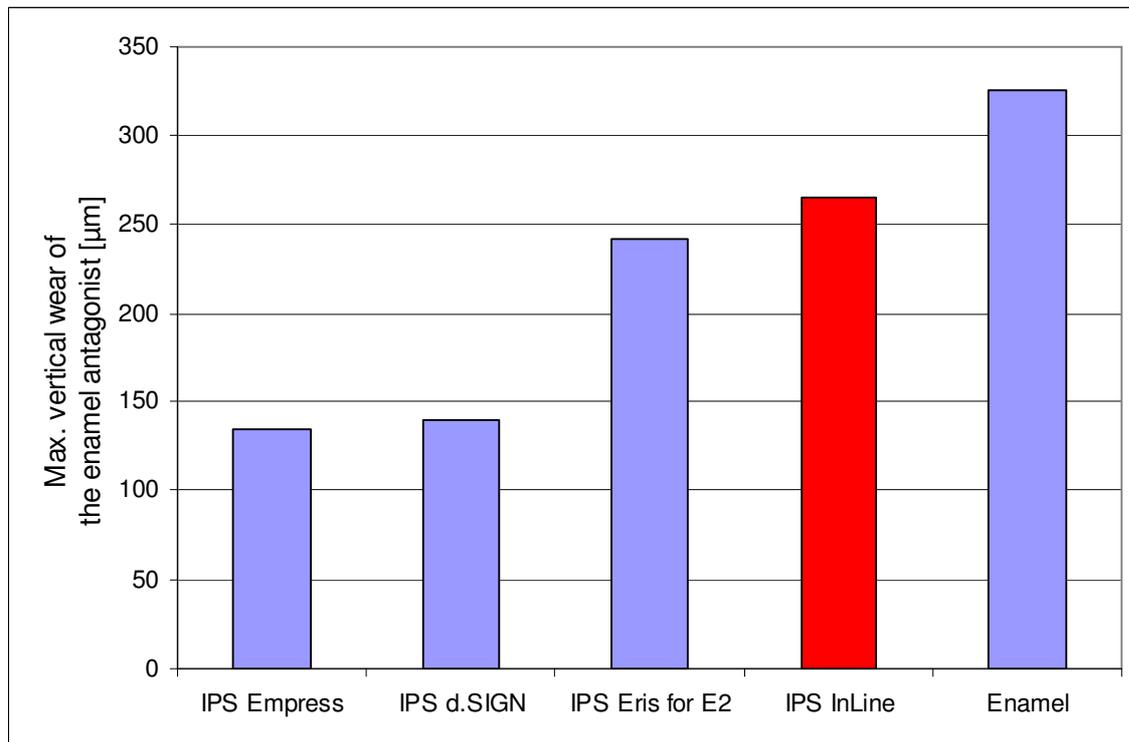


Fig. 19: In vitro tests in the chewing simulator: Antagonist wear (R&D, Ivoclar Vivadent AG, Schaan, 2004)

- The maximum wear of enamel antagonists by IPS InLine is comparable to that of clinically successful dental ceramics. As a comparison, the chart shows the antagonist wear of enamel under the same test conditions.

6.2.2 IPS InLine: Mean vertical wear – comparison with competitive materials

Material wear:

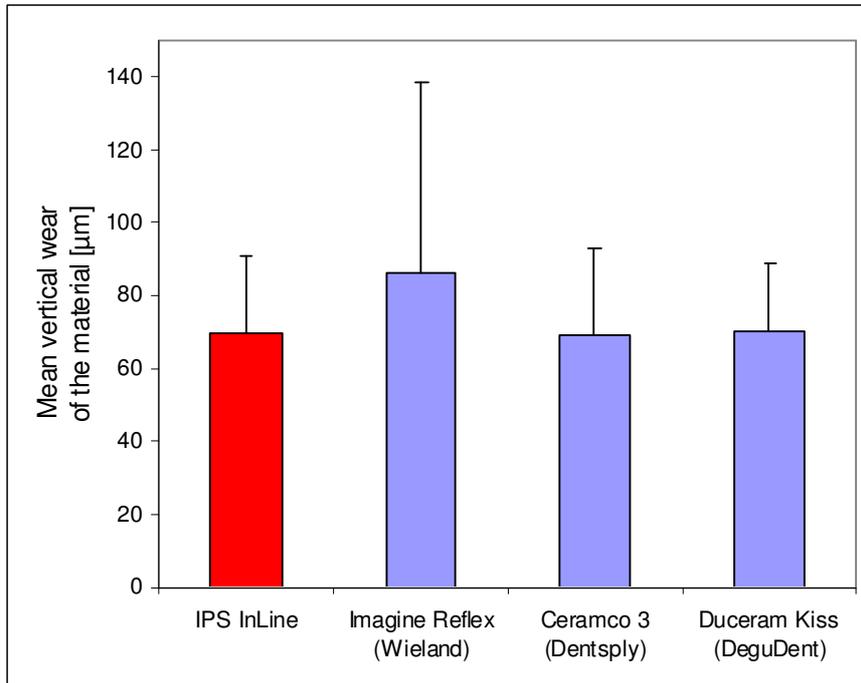


Fig. 20: Vertical wear of veneering ceramics (R&D, Ivoclar Vivadent AG, Schaan, 2005)

Antagonist wear:

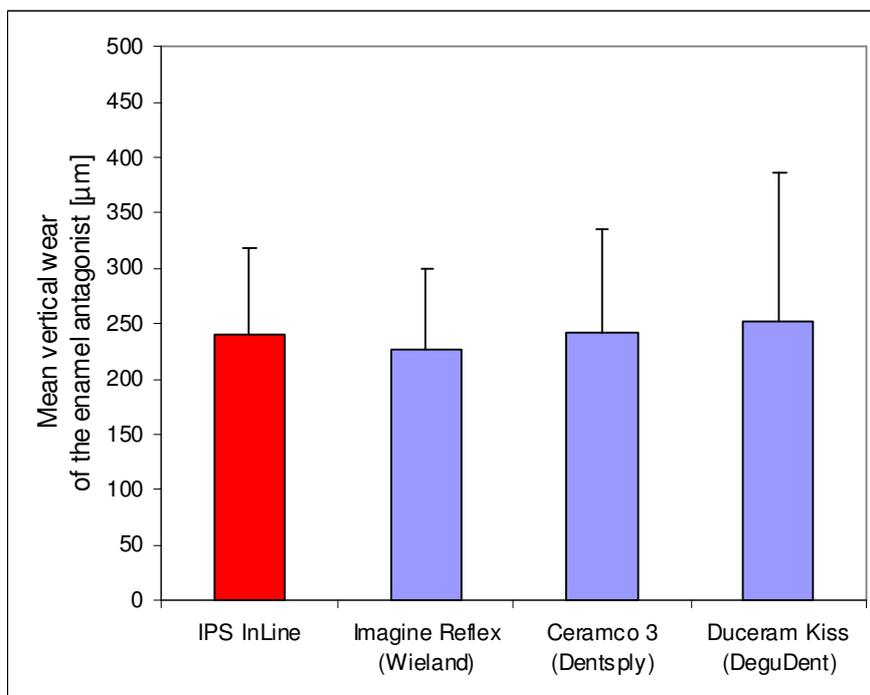


Fig. 21: Vertical wear of enamel antagonists (R&D, Ivoclar Vivadent AG, Schaan, 2005)

- The wear and antagonist wear of IPS InLine are comparable to the values of competitive products.

6.3 *Metal-ceramic bond*

The metal-ceramic bond of different alloys was determined with IPS InLine in compliance with ISO 9693 (test on crack initiation according to Schwickerath). The ceramic was bonded to the alloy specimen by conducting 2 opaquer firings, 2 dentin firings and a glaze firing.

A metal plate is fabricated of the alloy to be tested and the ceramic material fired onto it. The corresponding dimensions and fabrication procedure are described in the standard.

The test sample is secured in a universal testing machine and loaded with three-point bending load (Fig. 22). Subsequently, the force at which the delamination/crack formation is initiated is determined. The resulting force can be used to calculate the strength of the metal-ceramic bond.

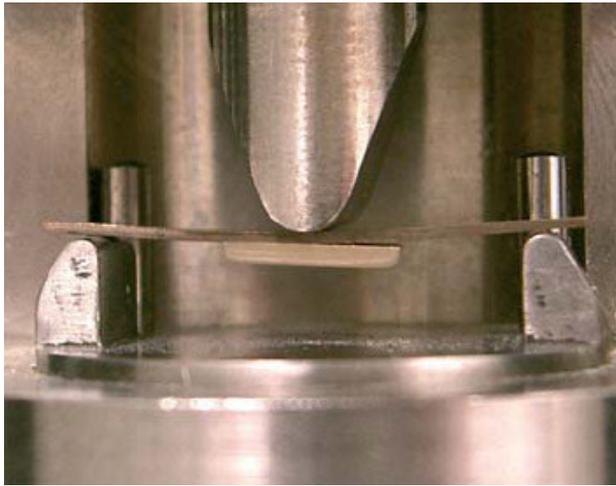


Fig. 22: Experimental Set-up of the bonding strength measurement³

³ Schnettger A., Fachhochschule Osnabrück, 2004

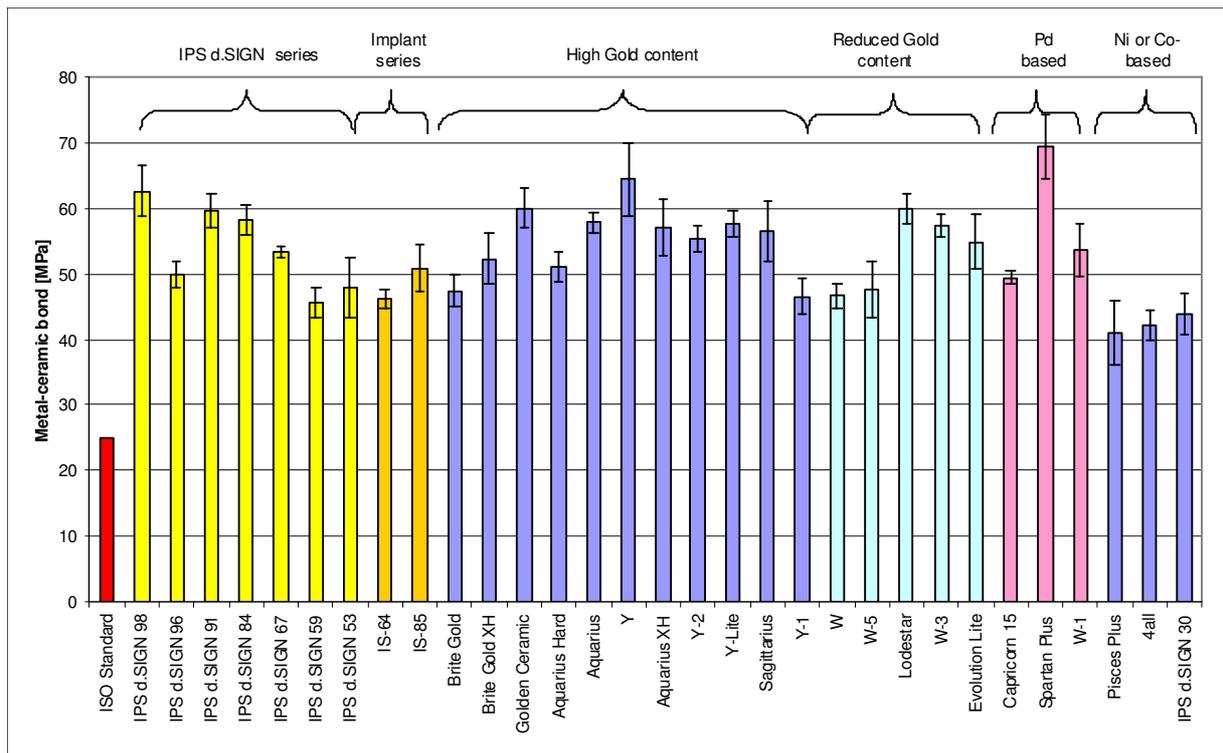


Fig. 23: Mean value and standard deviation of metal-ceramic bonds (number of samples per alloy: n=6) in conjunction with IPS InLine on different alloys [5]

- The metal-ceramic bond values of all the investigated alloys are clearly above the minimum value of 25 MPa stipulated in the ISO standard 9693.

6.4 List of alloys for the IPS InLine System

The following Ivoclar Vivadent alloys have been tested regarding their compatibility with IPS InLine One, IPS InLine and IPS InLine PoM. Detailed information and restrictions concerning product use can be found in the Instructions for Use.

Alloy	IPS InLine One IPS InLine	IPS InLine PoM IPS Investment Ring 100/200 g	IPS InLine PoM IPS Investment Ring 300 g	Colour	CTE 25–500°C
High gold					
Brite Gold	✓*	–	–	rich yellow	14.8
Brite Gold XH	✓*	–	–	rich yellow	14.4
Golden Ceramic	✓*	–	–	rich yellow	14.6
Aquarius Hard	✓*	✓ ²⁾	✓ ²⁾	rich yellow	14.5
Aquarius	✓*	–	–	rich yellow	14.6
IPS d.SIGN 98	✓*	✓ ¹⁾	–	rich yellow	14.3
Y	✓	–	–	yellow	14.6
Aquarius XH	✓	✓	✓	yellow	14.1
Y-2	✓*	–	–	yellow	15.0
Y-Lite	✓	✓	✓	yellow	13.9
Sagittarius	✓	✓	✓	white	14.0
Y-1	✓*	–	–	yellow	14.8
IPS d.SIGN 96	✓	✓	–	yellow	14.3
Reduced gold					
IPS d.SIGN 91	✓	✓	✓	white	14.2
W	✓	–	–	white	14.2
W-5	✓	–	–	white	14.0
Lodestar	✓	✓	✓	white	14.1
W-3	✓	✓	✓	white	13.9
Leo	✓	✓	✓	white	13.9
W-2	✓	✓	✓	white	14.2
Evolution Lite	✓	✓	✓	white	14.2
Palladium content					
Capricorn 15	✓	–	–	white	14.3
IPS d.SIGN 84	✓	✓ ²⁾	✓ ²⁾	white	13.8
Capricorn	✓	✓	✓	white	14.1
Protocol	✓	✓ ²⁾	✓ ²⁾	white	13.8
IPS d.SIGN 67	✓	–	–	white	13.9
Spartan Plus	✓	✓	–	white	14.3
Spartan	✓	✓	–	white	14.2
Callisto 75 Pd	✓	✓	✓	white	13.9
Aries	✓	–	–	white	14.7
IPS d.SIGN 59	✓*	–	–	white	14.5
IPS d.SIGN 53	✓**	–	–	white	14.8
W-1	✓*	–	–	white	15.2
Callisto CP+	✓	✓	✓	white	14.2
Implant alloys					
Callisto Implant 78	✓	✓	✓	white	13.9
IS -64	✓**	–	–	white	14.8
Callisto Implant 60	✓*	–	–	white	14.5
Free of precious metals					
Pisces Plus	✓	✓	✓	white	14.1
4all	✓	✓ ²⁾	✓ ²⁾	white	13.8
IPS d.SIGN 15	✓	✓	✓	white	13.9
IPS d.SIGN 30	✓**	✓ ²⁾	✓ ²⁾	white	14.5
Colado CC	✓**	✓ ²⁾	✓ ²⁾	white	14.2

Tab. 3: Ivoclar Vivadent alloys; tested regarding their compatibility with the IPS InLine System (Application instructions can be found in the Instructions for Use)

6.5 Metal-ceramic bond (re-cast alloys)

The re-casting of precious or reduced precious alloys is a common practice in dental laboratories. The effects of re-casting on the metal-ceramic bond were tested at the Ohio State University⁴. Contrary to common practice, a minimum of 50% new alloy was not added.

The bond of different alloys, such as Brite Gold XH (Au-Pt), W-5 (Au-Pd-Ag), IPS d.SIGN 53 (Pd-Ag), was tested in combination with IPS InLine.

The alloys were cast to metal plates. After oxide firing, IPS InLine was fused onto the centre of the metal plate. The same sample assemblies were fabricated of the same alloys after two and three re-castings without adding any fresh alloy. Each of the 9 test groups comprised 12 samples. The fracture load and bond strength values were determined according to EN ISO 9693.

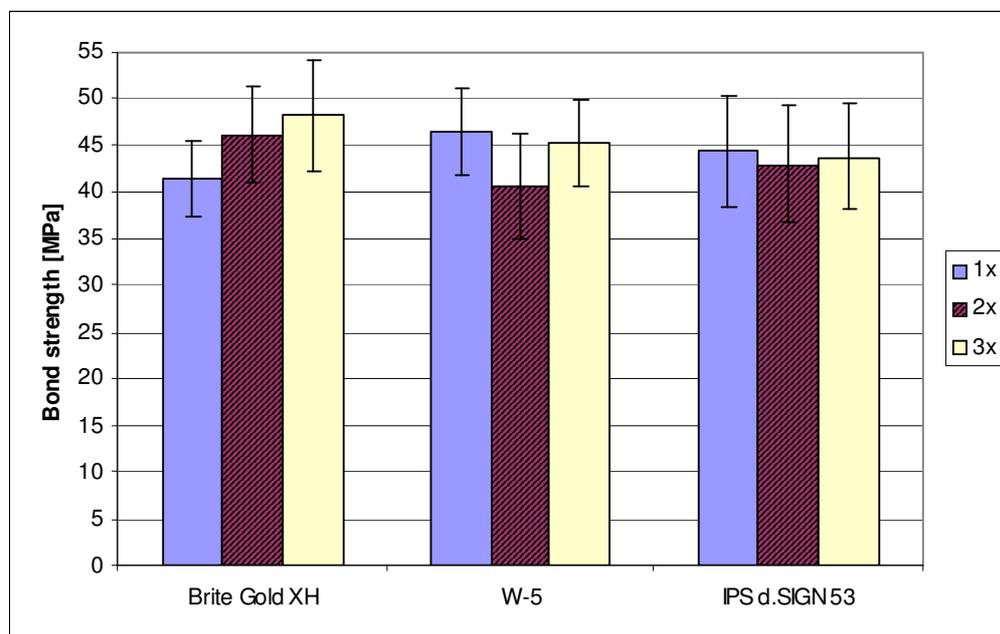


Fig. 24: Bond strength values of IPS InLine on 1-3x cast precious alloys⁴

- The repeated casting of the three precious alloys tested showed no effects on the metal-ceramic bond.
- All bond strength values are clearly above the minimum value of 25 MPa stipulated by the standard.

⁴ "Special update alloys 2/2006: Effects of re-casting without adding new alloy on the metal-ceramic bond", Ivoclar Vivadent, 2006

7. Clinical evaluation of the IPS InLine System

7.1 Clinical data

Leucite-containing veneering ceramics have been in clinical use for years. Their clinical success has been documented in numerous studies [6-15]. Using IPS InLine to veneer metal frameworks constitutes a standard application in restorative dentistry. It has been confirmed that veneering ceramics meet the requirements placed on them and do not entail an increased or unacceptable risk if they are used according to the manufacturer's instructions for use.

7.2 Clinical studies with IPS InLine (conventional metal-ceramic)

7.2.1 Italy

Head of study: Livio Benelli, Prato
Michele Temperani, Florence

Objective: Clinical examination on the esthetic quality and performance of metal-ceramic IPS InLine crowns and bridges on different metal frameworks.

Study design: Fabrication and insertion of 46 restorations (crowns, bridges, inlays, implant-borne restorations) on metals with a low, average and high CTE. Number of patients. 32.

Results⁵: After an observation period of more than two years, no fractures or chipping was recorded. In addition, the heads of the study point out a high resistance towards occlusal loading and attrition. It was possible to fabricate restorations with "exceptional esthetics".

7.2.2 Germany

Head of study: Jürgen Setz, Halle

Objective: Clinical comparison of composite and ceramic veneered, metal-supported crowns

Study design: Thirty posterior crowns each were veneered with IPS InLine and SR Adoro and inserted with a self-adhesive resin cement. High-gold alloys were used as framework materials.

Results: No negative incidents have been reported after two years.

7.3 Clinical studies with IPS InLine PoM (Press-on-Metal ceramic)

7.3.1 Germany

Head of study: Thomas Klink, Greifswald

Objective: Clinical evaluation of IPS InLine PoM

⁵ "Special update Metal-ceramics 1/2006: Clinical examination on the esthetic quality and performance of metal-ceramic IPS InLine crowns and bridges on different metal frameworks", Ivoclar Vivadent, 2006

Study design: Fabrication and insertion of 7 crowns and 7 bridges (total: 31 units). Metal frameworks made of IPS d.SIGN 30 (Co/Cr) and IPS d.SIGN 96 (high-gold).

Results: The press system has proven well so far. Neither chipping nor fractures were recorded during the observation period of up to one year. The easy pressing properties of the ceramic are highly appreciated.

7.3.2 USA

Head of study: Lyndon Cooper, Chapel Hill

Objective: Prospective clinical study with IPS InLine PoM crowns fabricated using the press-on technique.

Study design: Fabrication and insertion of 40 crowns.

Results: After one year, no problems or clinical complications have been reported.

7.3.3 Italy

Head of study: Carlo Monaco, Bologna

Objective: Clinical evaluation of IPS InLine PoM

Status: Press-on procedure of crowns in the posterior region. Forty-five frameworks each made of high-gold and zirconium oxide pressed over with IPS InLine PoM and IPS e.max ZirPress respectively.

Results: The purpose of this study is to examine the press-on techniques of frameworks made of metal alloys and zirconium oxide. Due to the different thermal and optical behaviour, the ingots of IPS InLine PoM for metal frameworks differ from those of IPS ZirPress for zirconium oxide frameworks.

After an observation time of 2 years, one case of chipping of a crown veneered with IPS InLine PoM has been reported. The crown was replaced.

7.3.4 Liechtenstein

Head of study: Ronny Watzke, Internal Clinic of Ivoclar Vivadent AG, Schaan

Objective: Clinical evaluation of metal-ceramic restorations

Study design: Examination of posterior bridges

Results: In a small series of 11 restorations (bridges) fabricated with IPS InLine PoM on various metal frameworks, data have been collected for a period of up to three years. No failures have been recorded. Minor chippings which were repaired intraorally by polishing have occurred in three restorations.

8. Biocompatibility

8.1 Introduction

A comparison of the technical data sheets of IPS InLine (Chapter 4) and IPS Classic (Scientific Documentation IPS Classic) shows that IPS InLine features the same standard composition as IPS Classic. Both materials have been developed for the same application. Based on investigations with IPS Classic, IPS InLine can be assumed to be biocompatible.

8.2 Biocompatibility

The ceramic materials used in dentistry are regarded as exceptionally "biocompatible" [16-18].

Biocompatibility may generally be regarded as a material's quality of being compatible with the biological environment [19], i.e. the material's ability to interact with living tissues by causing no or very little biological reactions. A dental material is considered to be "biocompatible" if its properties and function match the biological environment of the body and do not cause any unwanted reactions [20].

Ceramic materials have always enjoyed a good reputation as a biocompatible material [16; 21] and this reputation has steadily grown in the past forty years. This trend can certainly be attributed to the distinctive properties of these materials.

The volatile substances are eliminated in the course of the melting and sintering process involved in the manufacture of the ceramic. The high compatibility of this type of ceramic can be attributed to the following properties:

- Harmless ingredients (mainly oxides of silicon, aluminium, sodium and potassium) [16; 21; 22]
- Very low solubility [22]
- High stability in the oral environment; high resistance to acidic foods and solutions [16; 21]
- Low tendency to plaque formation [16; 21]
- No undesired interaction with other dental materials [16; 21]
- No chemical decomposition involving the release of decomposition products [16; 21]

These ceramics may be generally described as bioinert [19].

IPS InLine One, IPS InLine and IPS InLine PoM are leucite ceramics for the veneering of metal frameworks. Dental ceramics are known to demonstrate favourable biocompatible properties [17]. It can be assumed that the findings of general studies on the biocompatibility of dental ceramics also apply to the IPS InLine metal-ceramics.

8.3 Chemical solubility

Dental materials are exposed to a wide range of pH values and temperatures in the oral cavity. Therefore, chemical durability is an important prerequisite for dental materials.

According to Anusavice [16], ceramics are considered to be the most durable dental materials. The measurement of chemical solubility is defined by ISO 6872.

Chemical solubility according to ISO 6872:

Material	Chemical solubility [$\mu\text{g}/\text{cm}^2$]	Limiting value according to ISO 6872 [$\mu\text{g}/\text{cm}^2$]
IPS InLine/ IPS InLine PoM Opaquer A3	17.0	100
IPS InLine Dentin A2	25.1	100
IPS InLine Incisal T12	12.5	100
IPS InLine PoM ingot	50.0	100

Tab. 4: Chemical solubility of IPS InLine / IPS InLine PoM (internal measurement, Ivoclar Vivadent AG, Schaan, 2004/2007)

- The chemical solubility of IPS InLine and IPS InLine PoM is clearly below the limiting values stipulated in the standard.

8.4 In vitro cytotoxicity

The *in-vitro* cytotoxicity of IPS InLine [23-25] and IPS InLine PoM [26] was assessed by means of a XTT assay.

Under the selected test conditions, none of the tested samples has a cytotoxic potential.

8.5 Radioactivity

Concerns have been raised regarding the possible radioactivity of dental ceramics. The origin of these concerns date back to the seventies, when small amounts of radioactive fluorescent substances [27-29] were employed in various metal-ceramic systems. In this context, calculations as to a possible radiation level caused by dental ceramics were made [30]. Several alternatives to attain fluorescence in dental materials without using radioactive additives have become available since the eighties. We may therefore assume that all the major manufacturers stopped using radioactive ingredients in their materials from that time onwards. Nonetheless, possible sources of radioactivity cannot be so easily ruled out. Minute impurities of uranium or thorium in raw materials, which are sometimes used in their natural state, or in pigments are difficult to remove [27]. Consequently, the standards on ceramic materials (EN ISO 6872; EN ISO 9693; ISO 13356) prohibit the use of radioactive additives and stipulate the maximum level of radioactivity permissible in ceramic materials.

The following levels of radioactivity have been measured in IPS Classic and IPS InLine PoM by means of γ -spectrometry.

	^{238}U [Bq/g]	^{232}Th [Bq/g]
IPS Classic Dentin	< 0.010	<0.008
IPS Classic V - Opaquer	0.102	0.028
IPS Stains-P	0.140	0.048
IPS InLine PoM 3	< 0.03	< 0.03
IPS InLine PoM Touch Up 3	< 0.03	< 0.03
Threshold value	1,000	
ISO 6872 :1995/Amd.1:1997		

Tab. 5: Radioactivity of dental ceramics (Forschungszentrum Jülich 1997/ 2002/ 2007)

- The radioactivity of the tested ceramics is far below the limiting value specified in the relevant standard. (Comparison: The activity of the earth's crust is in the range of 0.03 Bq/g for ^{238}U and ^{232}Th)

8.6 Sensitization, irritation

Cavazos [31] and Allison *et al.* [32] have shown that, compared with other dental materials, dental ceramics cause no or only minimal adverse reactions when they come into contact with the oral mucous membrane. Mitchell [33] as well as Podshadley and Harrison [34] used implant tests to prove that glazed ceramics cause only very limited inflammation [33; 34] and thus far less irritation than other approved dental materials, such as gold and resin [34].

Since direct irritation of the mucous membrane cells through direct contact with ceramics can virtually be ruled out, possible irritation is generally attributable to mechanical stimulus. Normally, such reactions can be prevented by observing the IIPS InLine/IPS InLine PoM Instructions for Use.

- Ceramics has no or, compared with other dental materials, very little potential to cause irritation or sensitization.

8.7 Biological risk to user and patient

The dental technician is exposed to the highest risk potential (the risk to the dentist is rather negligible), as ceramic materials are frequently ground in the laboratory. The fine mineral dust created in the process should not be inhaled. This potential risk can be eliminated by using suction equipment and a protective mask. The dentist, who handles the completed restoration, is unlikely to face any risk at all. The biological risk posed to the patient is also very low. Ingestion of abraded ceramic particles or swallowing of delaminated ceramic may be considered harmless to the health of the patient. If the ceramic is used for the appropriate indication and adequately fitted to the dentition, local or systemic side effects are unlikely to occur [16; 35].

8.8 Conclusion

This synopsis shows that dental ceramics generally involve a very low hazard, while they offer a high level of biocompatibility. From this perspective, ceramic materials should be preferred for dental applications.

According to the available data, the current standard of knowledge and based on the clinical experience, both an acute and a chronic health risk can be practically excluded for all the parties that come in contact with the product, provided the IPS InLine System metal-ceramics are used according to the instructions of the manufacturer. A health risk for

patients, dental technicians and dentists can be excluded if the products are used according to the instructions of the manufacturer.

9. Literature

1. Claus H. Die Bedeutung des Leuzits für die Dentalkeramik. ZWR 1981;90:44-46.
2. Hinz W. Silicat Lexikon. Akademie Verlag Berlin; 1985.
3. Claus. Werkstoffkundliche Grundlagen der Dentalkeramik. Dental Labor 1980;28:1743-1750.
4. Sinmazisik G, Ovecoglu ML. Physical properties and microstructural characterization of dental porcelains mixed with distilled water and modeling liquid. Dent Mater 2006;22:735-745.
5. Schnettger A, Zylla I, F.Kappert H. Prüfung der Verbundfestigkeit metall-keramischer Systeme. Quintessenz Zahntechnik 2006;32:732-738.
6. Bischoff H. Opakdentin - Der Einsatz sichert den Erfolg. Quintessenz Zahntech 1992;18:1339-1347.
7. Bischoff H. Ein neues Material erleichtert die Auswahl. Dental Magazin 1995;3:88-89.
8. Kataoaka S. Das naturkonforme Cut-back - Basis jeder harmonischen Farbwirkung. Dent Labor 1995;43:201-210.
9. Schimbera T. Systematik bei der Herstellung einer individuellen Frontzahnbrücke. Dent Labor 1995;43:1821-1827.
10. Kühn T. Individualität und System - Ein Widerspruch in sich ? Dental Spectrum 1996;2:157-165.
11. Kühn T. Eine effiziente Schichttechnik bei einem gealterten Zahn: Individualität und System - ein Widerspruch in sich? Dental Spectrum 1996;1:271-275.
12. Brix O. Das Einmaleins der Metallkeramik. Das dental-labor 1998;9:1367-1374.
13. Brix O. Keramische Veneers mit Classic-V. Zahntech Mag 1998;10:590-596.
14. Brix O. Orale Harmonie durch Teamwork - Der sichere Weg zum natürlichen Ergebnis. Quintessenz Zahntech 1998;24:583-593.
15. Hadasch M. Aesthetische Restaurationen trotz ungünstiger funktioneller Verhältnisse. Dental Spectrum 1998;3:221-224.
16. Anusavice KJ. Degradability of dental ceramics. Adv Dent Res 1992;6:82-89.
17. McLean J. Wissenschaft und Kunst der Dentalkeramik. Quintessenz Verlags-GmbH; Berlin 1978.
18. Roulet J, Herder S. Seitenzahnversorgung mit adhäsiv befestigten Keramikinlays Quintessenz Verlags-GmbH, Berlin. 1989.
19. Ludwig K. Lexikon der Zahnmedizinischen Werkstoffkunde. Quintessenz Verlags-GmbH; Berlin 2005.
20. Wataha JC. Principles of biocompatibility for dental practitioners. The Journal of Prosthetic Dentistry 2001;86:203-209.
21. Anusavice K. Phillips' Science of Dental Materials. Eleventh Edition. W. B. Saunders Company Philadelphia; 2003.
22. Schäfer R, Kappert HF. Die chemische Löslichkeit von Dentalkeramiken. Deutsche Zahnärztliche Zeitschrift 1993;48:625-628.
23. Meurer K. Cytotoxicity assay in vitro: evaluation of materials for medical devices (direct cell contact test). RCC-CCR Report No. 878304. 2005.
24. Meurer K. Cytotoxicity assay in vitro: evaluation of materials for medical devices (direct cell contact test). RCC-CCR Report No. 878305. 2005.

25. Meurer K. Cytotoxicity assay in vitro: evaluation of materials for medical devices (direct cell contact test). RCC-CCR Report No. 878306. 2005.
26. Heppenheimer A. Cytotoxicity assay in vitro: Evaluation of materials for medical devices (XTT-Test). RCC-CCR Report No. 1120102. 2007.
27. Fischer-Brandies E, Pratzel H, Wendt T. Zur radioaktiven Belastung durch Implantate aus Zirkonoxid. Dtsch Zahnärztl Z 1991;46:688-690.
28. Moore JE, MacCulloch WT. The inclusion of radioactive compounds in dental porcelains. British Dental Journal 1974;136:101-106.
29. Viohl J. Radioaktivität keramischer Zähne und Brennmassen. Deutsche Zahnärztliche Zeitschrift 1976;31:860.
30. Sairenji E, Moriwaki K, Shimizu M, Noguchi K. Estimation of radiation dose from porcelain teeth containing uranium compound. J Dent Res 1980;59:1136-1140.
31. Cavazos E, Jr. Tissue response to fixed partial denture pontics. The Journal of Prosthetic Dentistry 1968;20:143-153.
32. Allison JR, Bhatia HL. Tissue changes under acrylic and porcelain pontics. J Dent Res 1958;37:66-67.
33. Mitchell DF. The irritational qualities of dental materials. J Am Dent Assoc 1959;59:954-966.
34. Podshadley AG, Harrison JD. Rat connective tissue response to pontic material. J Prosthet Dent 1966;16:110-118.
35. Mackert JR. Side-effects of dental ceramics. Adv Dent Res 1992;6:90-93.

This documentation contains a survey of internal and external scientific data ("Information"). The documentation and Information have been prepared exclusively for use in-house by Vivadent and for external Vivadent partners. They are not intended to be used for any other purpose. While we believe the Information is current, we have not reviewed all of the Information, and we cannot and do not guarantee its accuracy, truthfulness, or reliability. We will not be liable for use of or reliance on any of the Information, even if we have been advised to the contrary. In particular, use of the information is at your sole risk. It is provided "as-is", "as available" and without any warranty express or implied, including (without limitation) of merchantability or fitness for a particular purpose.

The Information has been provided without cost to you and in no event will we or anyone associated with us be liable to you or any other person for any incidental, direct, indirect, consequential, special, or punitive damages (including, but not limited to, damages for lost data, loss of use, or any cost to procure substitute information) arising out of your or another's use of or inability to use the Information even if we or our agents know of the possibility of such damages.

Ivoclar Vivadent AG
Research and Development
Scientific Services
Bendererstrasse 2
FL - 9494 Schaan
Liechtenstein

Contents: Dr Thomas Völkel
Issue: October 2010
